

Docket No. RDID01056 US



PATENT

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And H.A

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Effenhauser, Carlo et al.

Application No.: 09/943,080

Group No.: 1743

Filed: August 30, 2001

Examiner: To Be Assigned

For: SYSTEM FOR WITHDRAWING SMALL AMOUNTS OF BODY FLUID

Assistant Commissioner for Patents  
Washington, D.C. 20231

**PRELIMINARY AMENDMENT**

Sir:

Please enter the following amendments prior to examination of the above-referenced application:

IN THE CLAIMS:

Please amend claim 7 and claim 8 as follows:

In claim 7, line 1, delete "or 6".

In claim 8, line 1, delete "or 7".

Date: January 4, 2002

Respectfully submitted,

Richard T. Knaer, Reg. No. 35,575  
Roche Diagnostics Corporation  
9115 Hague Road, Bldg. D  
P.O. Box 50457  
Indianapolis, IN 46250-0457  
Telephone No.: (317) 521-7464  
Facsimile No.: (317) 521-2883



ersions With Markings to Show Changes Made

1. System for withdrawing small amounts of body fluid comprising a drive unit which has a holder which is moved from a first into a second position when the drive unit is activated, and a disposable lancing unit which has a holding area that is removably positioned in the holder, the proximal end of an elongate capillary structure comprising at least one capillary channel for transporting body fluid being connected to the holding area and the distal end of the capillary structure being suitable for piercing skin,  
  
wherein the distal end of the capillary structure is located outside the skin when the holder is arranged in said first position and in said second position is inserted into the skin up to the puncture depth, wherein  
  
the at least one capillary channel is open to the outside in an area which comprises at least a part of the longitudinal extension of the capillary structure.
2. System as claimed in claim 1, in which the entire length of the capillary structure from the proximal to the distal end is open to the outside.
3. System as claimed in claim 1, in which the holding area has a detection zone for detecting one or several analytes, the detection zone being arranged such that it can take up body fluid from the capillary structure.
4. System as claimed in claim 1, in which the drive unit moves the lancing unit in such a manner that it remains in the second position for a time interval (collection period) and, subsequently, the lancing unit is moved into a position in which the distal end of the capillary structure is outside the skin.

5. System as claimed in claim 1, in which the drive unit moves the lancing device in such a manner that after reaching the second position it is moved back into a collecting position in which a section of the capillary structure located in the skin is shorter than in the second position.
6. System as claimed in claim 1, in which the capillary structure and holding area are integrally connected together
7. System as claimed in claim 1 [or 6], in which the holding area and capillary structure are manufactured from a semiconductor preferably silicon.
8. System as claimed in claim 6 [or 7], in which the holding area and capillary structure are integrally manufactured from a single piece of material.
9. System as claimed in claim 1, in which the area of the capillary structure that is open to the outside has a channel shape.
10. System as claimed in claim 9, in which the channel-shaped area has an essentially V-shaped cross-section.
11. System as claimed in claim 1, in which the length of the capillary structure is in the range from 0.3 to 3 mm and the cross-section of the capillary structure is in the range from 0.03 to 0.8 mm.
12. Disposable lancing unit for withdrawing small amounts of body fluid which has a holding area to which the proximal end of an elongate capillary structure is connected, said capillary structure comprising at least one capillary channel to transport body fluid and the distal end of the capillary structure is suitable for piercing skin, wherein

an area of said at least one capillary channel which comprises at least a part of the longitudinal extension of the capillary structure is open to the outside.



Clean Copy of Claims

1. System for withdrawing small amounts of body fluid comprising a drive unit which has a holder which is moved from a first into a second position when the drive unit is activated, and a disposable lancing unit which has a holding area that is removably positioned in the holder, the proximal end of an elongate capillary structure comprising at least one capillary channel for transporting body fluid being connected to the holding area and the distal end of the capillary structure being suitable for piercing skin,  
  
wherein the distal end of the capillary structure is located outside the skin when the holder is arranged in said first position and in said second position is inserted into the skin up to the puncture depth, wherein  
  
the at least one capillary channel is open to the outside in an area which comprises at least a part of the longitudinal extension of the capillary structure.
2. System as claimed in claim 1, in which the entire length of the capillary structure from the proximal to the distal end is open to the outside.
3. System as claimed in claim 1, in which the holding area has a detection zone for detecting one or several analytes, the detection zone being arranged such that it can take up body fluid from the capillary structure.
4. System as claimed in claim 1, in which the drive unit moves the lancing unit in such a manner that it remains in the second position for a time interval (collection period) and, subsequently, the lancing unit is moved into a position in which the distal end of the capillary structure is outside the skin.

5. System as claimed in claim 1, in which the drive unit moves the lancing device in such a manner that after reaching the second position it is moved back into a collecting position in which a section of the capillary structure located in the skin is shorter than in the second position.
6. System as claimed in claim 1, in which the capillary structure and holding area are integrally connected together.
7. System as claimed in claim 1, in which the holding area and capillary structure are manufactured from a semiconductor preferably silicon.
8. System as claimed in claim 6, in which the holding area and capillary structure are integrally manufactured from a single piece of material.
9. System as claimed in claim 1, in which the area of the capillary structure that is open to the outside has a channel shape.
10. System as claimed in claim 9, in which the channel-shaped area has an essentially V-shaped cross-section.
11. System as claimed in claim 1, in which the length of the capillary structure is in the range from 0.3 to 3 mm and the cross-section of the capillary structure is in the range from 0.03 to 0.8 mm.
12. Disposable lancing unit for withdrawing small amounts of body fluid which has a holding area to which the proximal end of an elongate capillary structure is connected, said capillary structure comprising at least one capillary channel to transport body fluid and the distal end of the capillary structure is suitable for piercing skin, wherein  
  
an area of said at least one capillary channel which comprises at least a part of the longitudinal extension of the capillary structure is open to the outside.